

### **REMARKS**

Claim 2 – 5, 7 – 9, 20 and 21 are currently pending. Claims 5, 20, and 21 are the pending independent claims. Claims 6 and 19 are cancelled herein and new Claims 20 and 21 have been added.

In the Office Action, Claims 2 – 4, 8, 9, and 19 were rejected under Section 112, first paragraph as allegedly failing to comply with the enablement requirement. Claims 2 – 4, 6 – 9, 19 were also rejected under Section 112, second paragraph, as allegedly indefinite for various reasons.

Each of the foregoing rejections is respectfully traversed and favorable reconsideration is requested in view of the above amendments and following remarks.

I. Enablement / Indefiniteness Rejections of Claims 2 – 4, 8, 9, and 19.

As an initial matter, the Examiner contends that Claims 2 – 4, 8, 9, and 19 either “cannot be considered enabled” or, in the alternative, “are not written properly.” In total, the Examiner raises four separate points in regard to these contentions.

First, the Examiner notes that Claim 19 has “two branches”, one in which the “silylated starting material” IIB is used, and one in which the “non-silylated starting material” IIA is used. The Examiner contends that, when the non-silylated starting material IIA is used and  $n = 0$ , no provision is made for the hydrohalide (HX) specified in product V.

Applicants first draw the Examiner’s attention to the fact that they have cancelled Claim 19 and replaced it with new independent Claims 20 and 21. Claim 20 is directed to a process for making the formula I compound in which the formula IIA compound is reacted with a “reactive” derivative of a compound according to formula III. Claim 21 is directed to a process in which material according to formula IIB is reacted with a “reactive” derivative of formula III. In the Claim 20 process,  $n$  is now permitted to be either 1 or 2, eliminating the  $n = 0$  situation the Examiner has pointed out.

In the Examiner's second and third points, he notes that the final product in Claim 20 is specified to be a dihydrochloride, while the formula IIA material may be either a chloride, bromide, or iodide. The Examiner questions how the compound can be converted to a dihydrochloride according to the scope of the claimed process which allows for the possibility of using other halogens besides chloride in the compound of formulas IIA or IIB.

In response, independent Claims 20 and 21 have been amended to specify that, according to the claimed process, salt forms that may be present are optionally removed and then reacted with hydrochloric acid from an aqueous acetonic solution to convert the compound to its dihydrochloride form. Removal of the salt form may take place by ion exchange for example, as described in the Applicants' specification at page 5, or by such other procedure as is known or hereafter known to a person of ordinary skill.

In the Examiner's fourth point, he notes that the final product is a monohydrate and questions where the water for this hydrate comes from. As discussed above, the claims now specify the free base or other suitable form of compound V is reacted with hydrochloric acid from an aqueous acetonic solution. The use of an aqueous acetonic solution (containing HCL) allows for the formation of the monohydrate salt to produce the compound of formula I. In addition, Claim 20, as amended herein, also allows for the possibility that the compound of formula IIA is initially provided as a hydrate.

In view of these amendments, it is submitted that the enablement / indefiniteness rejections has been overcome and should now be withdrawn.

## II. Indefiniteness Rejections of Claims 3 and 4.

The Examiner also contends that Claims 3 and 4 are indefinite because, in his view, these claims use the compound of formula IIA in the form of a "monohydrate" or a "solvated" form, but that no provision for this hydrate or solvate is made in Claim 19.

Once again, however, Claim 20 now allows for the possibility that the compound of formula IIA is initially provided as a hydrate. Further, the claims now specify that

hydrochloric acid is provided from an aqueous acetonic solution to make the monohydrate chloride salt. Thus, the addition of the aqueous acetonic solution allows for the hydration of the salt.

In view of these amendments, it is submitted that the indefiniteness rejection has been overcome and should now be withdrawn.

III. Indefiniteness Rejections of Claims 6 and 7.

The Examiner also contends that Claim 6 and its dependent Claim 7 are indefinite because the “free base” form is no longer embraced by the scope of Claim 6 when m is 1. In response, Claim 6 has been cancelled, and Claim 7 has been amended to depend from Claim 5 instead.

In view of these amendments, it is submitted that the indefiniteness rejection has been overcome and should now be withdrawn.

IV. Indefiniteness Rejections of Claims 8, 9, and 19.

Finally, the Examiner contends that Claims 8, 9, and 19 are, in his view, indefinite because (1) Claim 19 improperly refers to “silyl protecting groups” in the plural, rather than the singular, and (2) the phrase “if present” is improper since Formula IV requires a trialkylsilyl group.

In response, both “silyl protecting groups” and “if present” have been removed from new Claim 20. In new Claim 21, the phrase “if present” is removed and the “silyl protecting group” is referred to in the singular to cover one or more such groups.

In view of these amendments, it is submitted that the indefiniteness rejection has also been satisfactorily addressed or overcome, and should also be withdrawn.

In light of the foregoing, Applicants urge the Examiner to reconsider the application, to withdraw the rejections, and to issue a notice of allowance at the earliest possible convenience.

Application No. 10/552,858  
May 13, 2009

In the event this response is not timely filed, Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our Deposit Account No. 12-2355.

Respectfully submitted,

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